Remarks

The claims from the PCT application, which were designed to facilitate global filings, have been amended to present the claimed invention in better accordance with U.S. practice.

The Swiss style claims 1-18 are being deleted in favor of the method of treatment Claims 24-28, and 31-55, which are in accordance with the favored U.S. practice. Claims 29 and 30 are being deleted in favor of Claim 34 and new Claim 55, as covering the similar subject matter. Claim 33 is being deleted without prejudice against the filing of divisional or continuation applications to cover the same subject matter.

Claims 21, 27, 31, 32, 37, 40, 46, and 50 have merely been rewritten in independent form. In rewriting Claim 27 in independent form, Applicants have also, without prejudice, included the limitation of claim 25 to more particularly and distinctly claim one preferred embodiment of the present invention. In rewriting Claim 37 in independent form, Applicants have also, without prejudice, included the limitation of claim 35 to more particularly and distinctly claim another preferred embodiment of the present invention.

New Claim 55 is fully supported throughout the specification and especially at page 20, line 31 through page 21, line 1.

No new subject matter is added to the application. A clean copy of the entire claim set as amended is enclosed, for the Examiner's convenience.

Respectfully submitted,

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Amended Claims In Mark-Up Form

21. (Amended) An article of manufacture [according to Claim 20] comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is effective for treating premature ejaculation in a human male, and wherein said packaging material comprises a label which indicates that said pharmaceutical agent can be used for treating premature ejaculation in a human male on an as-needed basis prior to a sexual activity, and wherein said pharmaceutical agent comprises dapoxetine or a pharmaceutically acceptable salt thereof, and wherein the label indicates that the dapoxetine is to be administered about immediately prior to, to about 4 hours prior to a sexual activity.

27. (Amended) [The] A method [according to claim 26] of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor, wherein the sexual dysfunction is premature ejaculation and the mammal is a human male.

31. (Amended) [The] A method [of claim 24] of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor, wherein said rapid-onset selective serotonin reuptake inhibitor is short acting.

32. (Amended) [The] A method [of claim 24] of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor, wherein said rapid-onset selective serotonin reuptake inhibitor is delivered in a rapid release formulation.

37. (Amended) [The] A method [of claim 36] of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a

pharmaceutically acceptable salt thereof, wherein the sexual dysfunction is premature ejaculation and the mammal is a human male.

40. (Amended) [The] A method of [claim 37] treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the sexual dysfunction is premature ejaculation, wherein the mammal is a human male, and wherein dapoxetine is administered immediately prior to, to about 4 hours prior to a sexual activity.

46. (Amended) [The] A method of [claim 34] treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.1 mg to about 120 mg.

50. (Amended) [The] A method of [claim 34] treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein dapoxetine or its pharmaceutically acceptable salt is delivered as a rapid release formulation.